

REMARKS

State of the Claims

Claims 1-50 are pending. Claims 6, 29 and 50 have been amended to resolve non-prior art related issues. No new matter has been added.

35 U.S.C. § 112 Rejection

Claim 6 stands rejected under 35 U.S.C. § 112, first paragraph, because the Examiner asserts that the specification, while being enabling for the addition of an "asparagines-reducing enzyme" (i.e., asparaginase), does not reasonably provide enablement for any random method reaction of "reducing the level of asparagines" in a food material.

Applicants have amended Claim 6 to make it dependent upon Claim 5. Claim 5 is properly enabled by the specification, and the subject matter of Claim 6 adds to it the reduction of asparagine prior to heating of the food product, a process which is also enabled by Applicants' specification.¹ Nonetheless, Applicants reserve the right to pursue the subject matter of Claim 6 as originally filed in a later divisional application. Applicants expressly do not agree that the subject matter of original claim 6 is not enabled by the specification.

Thus, Applicants believe that Claim 6 should be reconsidered and allowed over the Examiner's 35 U.S.C. § 112, first paragraph, rejection.

Claims 1-5, 7-32 and 45-50 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

The Examiner states that the term "reduced" in Claims 11-32 and 45-50 is indefinite. The Examiner further states that the term 'reduced' "is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention."

Applicants respectfully disagree with the Examiner's assertions. First, Applicants point out that the claims alone do not have to define the term "reduced". Rather, the specification can provide the proper basis for definition of any term used in the claim. Applicants assert that the specification does in

¹ Applicants' Specification at page 3, lines 16-18: "Applicants have found that adding an enzyme that hydrolyzes the amide group on the side chain of asparagine prior to heating (e.g., cooking) the food reduces the level of acrylamide present in the finished food product." [Emphasis added.]

fact provide the proper definition and understanding of the term “reduced” as it relates both to asparagine-reduction and acrylamide-reduction.²

In addition, common usage of a term can provide definition for claim terms. For example, the term “reduced”, in common usage, is defined as “to lessen in extent, amount, number, degree or price.” The American Heritage Dictionary, 2nd Ed., Houghton Mifflin Company, Boston (1991). Such definition bolsters Applicants’ use of the term in their specification since Applicants teach the reduction of the amount of acrylamide in thermally processed foods in comparison to foods not treated for such acrylamide reduction.³

Whether one skilled in the art looks to the specification or to common usage, it would be obvious to one skilled in the art that the term “reduced,” as used in the presently rejected claims, means that the level of asparagine/acrylamide is less in the claimed food material than it would ordinarily be in untreated food material, i.e. food material not exposed to asparagine-reducing enzymes. Thus, the term “reduced” means that the food material has been treated with an enzyme such that the level of asparagine/acrylamide is less than what it would be in untreated food material.

Applicants respectfully assert that one skilled in the art would understand that the use of the term “reduced” in the present claims describes the level of asparagine or acrylamide in treated food material as compared to the level present in untreated food material. Therefore, it is respectfully asserted that the term “reduced” in the presently rejected claims does indeed provide a standard for ascertaining the meaning, such that one skilled in the art would be reasonably apprised of the scope of the claimed invention.

As such, Applicants respectfully request reconsideration and allowance of Claims 1-5, 7-32 and 45-50 over the Examiner’s 35 U.S.C. § 112, second paragraph, rejection.

Claims 1-5 and 7-10 stand rejected over the Examiner’s 35 U.S.C. § 112, second paragraph, rejection.

Specifically, the Examiner states that asparagine is “not an actual oxido-reductase class of enzymes,” but rather, belongs to the hydrolase class of enzymes. The Examiner continues by saying that “while Applicant presumably intends this term to broadly encompass any enzyme which reduces the amount of asparagine in the product, it is technically improper.” Finally, the Examiner concludes by quoting Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350 (Fed Cir. 1999) which says that where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to

² Id.

³ Id. at page 3, lines 12-15: “Accordingly, Applicants have further discovered that acrylamide formation in heated foods can be *reduced* by removing the asparagine or converting the asparagine in the food to another substance before cooking. When such foods containing *reduced levels* of asparagine are heated, the amount of acrylamide formed is reduced.” [Emphasis added].

its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term.

Applicants respectfully traverse this rejection. The term “reducing,” as used within the phrase “asparagine-reducing enzyme,” refers not to a class of enzymes, but rather to their functionality. Moreover, contrary to the Examiner’s contention, the term “asparagine-reducing enzyme” is fully defined in the present specification. Specifically, in the present specification, both of the foregoing concerns are addressed as the term “asparagine-reducing enzyme” is defined as “any enzyme capable of reducing the *level* of asparagine in a food product.”⁴ [Emphasis added.] There is no mention of enzyme class or reduction reactions, such that one skilled in the art would be misled as to the meaning of the term as the Examiner claims. Indeed, in light of the foregoing definitions, Applicants respectfully assert that “asparagine-reducing enzyme” is clearly defined in the present specification such that one skilled in the art would understand that “asparagine-reducing” relates to the level of asparagine rather than the class of the enzyme described therein. For these reasons, Applicants respectfully traverse the Examiner’s rejection of the use of the term “asparagine-reducing enzyme” under the second paragraph of §112.

Therefore, Applicants respectfully request reconsideration and allowance of Claims 1-5 and 7-10 over the Examiner’s 35 U.S.C. § 112, second paragraph, rejection.

Claims 46 and 48 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner states that the term “low” used herein is a relative term which renders the claims indefinite. The Examiner states that the term “low” is not defined by the claims, that the specification does not provide a standard for ascertaining the requisite degree, and that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Lastly, the Examiner states that there is no standard or original amount of acrylamide provided in the specification such that one skilled in the art (or a consumer of the claimed article) would be apprised of what constituted a “low” amount of acrylamide within the article.

Applicants respectfully disagree with the Examiner. First, Applicants point out that Claims 46 and 48 are article of commerce claims and as such are claiming the communication of a “low” level of acrylamide in the food product. Such a communication is amply supported by the specification. For example, in several of the examples in the specification, the following is read:

EXAMPLE 5 – Article of Commerce

The potato chips of Example 2B are packaged in a bag for sale to consumers. *Printed on the bag is a message stating, “Low in acrylamide!”* [Emphasis Added.]

⁴ Id. at page 4, lines 18-19.

EXAMPLE 6 – Article of Commerce

The potato chips of Example 2C are packaged in a bag for sale to consumers. Printed on the bag is a message stating, “Acrylamide reduced by over 90%!” *A television commercial for the chips communicates the message, “Our chips are lower in acrylamide!”* [Emphasis Added.]

EXAMPLE 10 – Article of Commerce

The potato chips of Example 2C are packaged in a bag for sale to consumers. *Printed on the bag is a message stating, “Made from ingredients low in asparagine!”* [Emphasis Added.]

In Claims 46 and 48, the message informs the consumer that the food product is low in acrylamide. Applicants assert that one of skill in the art would, by the claims themselves and from Applicants’ specification, understand that the invention is an article of commerce that has as part of its packaging or advertising a message communicating the “low”-ness of acrylamide and the reduction thereof. Applicants further assert that a consumer reading this message would understand what this “low”-ness is intended to convey without, as the Examiner puts it, providing “a standard for ascertaining the requisite degree” of the “low”-ness of the acrylamide.

Furthermore, Applicants respectfully point out that the term “low” as used in claims 46 and 48 is simply a word on a label, and thus, there is no definiteness issue surrounding its use in this context. A label either displays the term “low,” or a similar term, or it doesn’t. Therefore, because the presently rejected claims relate only to the labeling of the product, rather than the potato products, it is irrelevant what the term “low” actually means in these claims. (It will be left to the appropriate regulatory body to determine whether the use of the term “low” on a label, as claimed herein, is proper).

Thus, Applicants respectfully assert that the Examiner’s rejection of Claims 46 and 48 should be obviated and allowed to issue over the Examiner’s 35 U.S.C. § 112, second paragraph, rejection.

35 U.S.C. § 103 Rejection

Claims 1-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Elder, et al. (U.S. Patent Application No. 2004/0058054--hereinafter, Elder ‘054).

The Examiner states that Elder ‘054 discloses a method for reducing the amount of acrylamide in thermally processed foods whereby an example of a thermally processed food ingredient is potato flakes. The Examiner points out that Elder ‘054 discloses contacting asparagine with the enzyme asparaginase. The Examiner further notes that Elder ‘054 provides in Example 5 proof that acrylamide reduction was reduced by more than 99.9%. The Examiner then sums up by stating that it would have been obvious to one of ordinary skill in the art to have added an asparaginase enzyme to a variety of fried food in order to reduce the level of asparagine within the food product.

The Examiner bears the burden of factually supporting any prima facie conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. See Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fe. Cir. 1983). Distilling the invention down to the “gist” or “thrust” of an invention disregards the requirement of analyzing the subject matter “as a whole.” See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983). Inventors of unobvious compositions, such as those of the present invention, enjoy a *presumption* of non-obviousness, which must then be overcome by the Examiner establishing a case of prima facie obviousness by the appropriate standard. If the Examiner does not prove a prima facie case of unpatentability, then without more, the Applicant is entitled to grant of the patent. See In re Oetiker, 977 F.2d 1443.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all of the claim limitations.⁵

Applicants respectfully disagree with the Examiner and assert that Elder ‘054 not only does not teach or suggest Applicants’ invention but also fails to reduce to provide an expectation of success between its examples, particularly example no. 5, and the claimed subject matter of Elder ‘054, namely reducing the presence of acrylamide in thermally processed food. In so doing, Elder ‘054 has failed to appreciate the difficulty in adding or applying an asparagine-reducing enzyme to food.

To begin, Applicants note that there are stark differences between 1) Applicants’ forms of food like dehydrated potato flakes versus a simple sugar and amino acid and 2) reducing the levels of asparagine and/or acrylamide in food versus that of simple sugar and amino acid. Looking carefully at the Example Nos. 1-5 of Elder ‘054, one is struck by the fact that the reduction of either asparagine or acrylamide is **never achieved in food**. Rather, Elder ‘054 merely adds simple sugar to amino acid in test vials, heats the materials, adds asparaginase and then records, essentially, the reaction of asparaginase to the sugar/amino acid combination in the way of reduced levels of acrylamide formed. More specifically, Elder ‘054 only shows the reduction of acrylamide in one example, namely, Example No. 5. In Example No. 5, glucose is added to asparagine and then heated to form acrylamide. Next, asparaginase is added to the glucose/asparagine mix. Subsequently, the acrylamide levels are measured and compared with two untreated controls. Although a reduction in acrylamide is shown, Applicants assert that such experiments

⁵ In re Vaeck, 947 F. 2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

without more do not provide an expectation of success that one of skill in the art reading Elder '054 would be able to reduce asparagine/acrylamide in food. Elder's Example No. 5 is limited only to test vials with ingredients that cannot fairly be said to be food. Rather, the components glucose and asparagine are components of food that lack the complex structure of most foods, e.g., potato-based foods, that perform well in a test vial, because none of Applicants' work to break down food to reduce acrylamide levels need be performed by Elder '054.

Furthermore, Elder '054 only mentions that asparaginase can be used to come into "contact" with the simple sugar/amino acid combination. Other than putting asparaginase in the test tubes of Example No. 5, the nature of this "contact" is never explained, defined or taught. Applicants' "contact" of their asparagine-reducing enzyme is much more robust and definitive.⁶ Applicants provide no less than 3-5 pages of disclosure detailing their break-through ability of adding an asparagine-reducing enzyme to food, e.g., potato in order to reduce asparagine levels. Such detailed addition is necessary because of the nature of food, and in particular potato products which have a cellular structure that is difficult to either break-down or weaken and penetrate with an enzyme or any other substance. One of skill in the art knows that in order to penetrate the cell walls of, say, potato flakes, much work and energy must be applied to the flakes in order to reach the interior of the potato cells; i.e., the cite where asparagine is produced in potato cells. Such difficulty is not even hinted at by Elder '054 much less taught or suggested.

In addition and importantly, there is no reasonable expectation of success as Elder '054 fails to teach a method for acrylamide reduction in any food, much less in potato-based foods. Elder '054 generally discusses "inactivating asparagine" in foods, yet fails to provide any practical teachings relating thereto, even though the claims are directed to food products. Moreover, there is no teaching or suggestion in either the examples, or the specification, of Elder '054 of a method by which to reduce the level of asparagine or acrylamide in a food product (e.g., potato-based foods) by, for example, at least about 10%, at least about 30%, etc., up to at least about 90%, as presently taught and claimed by Applicants. Similarly, there is no teaching or suggestion in Elder '054 of food having acrylamide levels

⁶ Applicants' Specification at page 4, lines 32-36 to page 6, lines 1-10; at page 4, lines 32-36 to page 5, lines 1-8: "The enzyme may be added to the food material in any suitable form. For instance, the enzyme may be added as a powder or in the form of a solution. Furthermore, the enzyme may be added to the food material in any suitable manner, such as directly (for example, sprinkled, poured, or sprayed on the food material) or indirectly. In one embodiment, the enzyme is admixed with a food that does not contain asparagine, then the resulting mixture is added to the asparagine-containing food. In another embodiment, at least a portion of the asparagine is extracted from the food material, the resulting extract is treated with the enzyme, then at least a portion of the extract is added back into at least a portion of the food material; for example, the enzyme may be added to the stream, or the stream may be pumped through a bed or column of immobilized enzyme (enzyme either adsorbed or chemically bonded to a substrate, preferably an inert substrate, e.g., pieces of plastic or beads in a column). [Applicants' disclosure is replete with this kind of detailed teaching.]

below about 300 ppb, below about 200 ppb, etc. down to a level below about 10 ppb, as presently taught and claimed by Applicants. Rather, the Elder '054 examples test only a chemical reaction (or the inhibition thereof) of a few chemicals independent of any food product.

Specifically, contrary to the Examiner's assertion in the last sentence on page 5 of the Action, Example 5 in Elder '054 deals only with the combination of asparagine, glucose and asparaginase in a laboratory setting. (Notably this is the only example having anything to do with *preventing* acrylamide formation.) There is no showing that such an example is in any way representative of what would occur if the method disclosed therein was carried out using an actual food product. Without such a correlation, it cannot be said that Elder '054 teaches the subject matter of Applicants' independent claims. As a result, it cannot be said that Elder '054 provides *any* likelihood or expectation that the findings presented therein could be produced in food products. Therefore, Applicants respectfully assert that because Elder '054 merely sets forth very general assertions about acrylamide reduction in certain food products, it provides no reasonable expectation of success of providing any food and in particular any potato-based food products with reduced acrylamide or asparagine levels. For this additional reason, Applicants respectfully assert that a *prima facie* case of obviousness has not been established.

As such Elder '054 has not taught or suggested Applicants' invention and furthermore has merely made unsubstantiated food-related assertions based on examples that do not teach or suggest the reduction of asparagine/acrylamide in food.

Applicants therefore respectfully request reconsideration and allowance of Claims 1-50 over the Examiner's 35 U.S.C. § 103(a) rejection in view of Elder '054.

Double Patenting - Non-Statutory

Claims 1-50 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over various claims of co-pending Application Nos. 10/606,260, 10/603,279, 10/603,978, 10/603,973 and 10/603,278.

Applicants respectfully traverse these rejections. Applicants submit that the Examiner has failed to provide sufficient basis for asserting that the cited claims of the 10/606,260, 10/603,279, 10/603,978, 10/603,973 and 10/603,278 applications teach or suggest the claims of the present application which are directed to reducing asparagines or acrylamide in food. Accordingly, it is respectfully requested that the obviousness-type double patenting rejections be withdrawn.

Double Patenting - Statutory

Claims 45-46 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of Claims 13-14 of co-pending Patent Application No. 10/603,978.

Applicants have not canceled Claims 45 and 46 herein. Instead, Applicants may amend or cancel Claims 13 and 14 in the co-pending patent application to alleviate the Examiner's rejection herein.

Thus, Applicants respectfully request reconsideration and allowance of Claims 45 and 46 over the Examiner's 35 U.S.C. § 101 (Statutory Double Patenting) rejection.

SUMMARY

The rejections in the Office Action have been discussed and, Applicants believe, the proper discussions and/or amendments have been set forth to address the rejection.

In light of both the amendments and the discussions contained herein, Applicants respectfully request reconsideration of the rejection and its withdrawal.

Issuance of a Notice of Allowance at an early date is earnestly solicited.

Respectfully submitted,

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December 2, 2004

Customer Number 27752